

EXHIBIT 8

AUSTRALIA

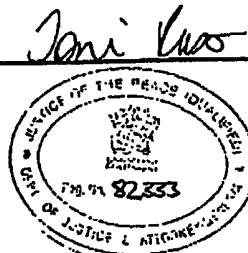
Patents Act 1990

IN THE MATTER OF
US Patent Application No. 09/446,109
by The University of Queensland

EXHIBIT SMT-8

This is Exhibit SMT-8 referred to in the Statutory Declaration by Stephen Maxwell Taylor
dated 12 MAY 2004

Before me:



A person empowered to witness Statutory
Declarations under the laws of the Queensland,
Commonwealth of Australia

PRM-01-03

Open Label Safety and Tolerability Study of Topical PMX53 in Subjects with Psoriasis

Psoriasis Trial

- **Primary Objective**
 - Evaluate the safety and tolerability of topically administered PMX53 twice daily for 56 days to target lesions of subjects with psoriasis
- **Secondary Objective**
 - Evaluate the effect of topical administration of PMX53 on disease status of target lesion

Psoriasis Trial

- Single dose application in healthy volunteers
 - 3 subjects, single application
- Multiple dose application in healthy volunteers
 - 3 subjects, twice daily 4 days
- Multiple dose application in psoriasis patients
 - PMX53 Gel (10mg/ml) will be applied to target lesion twice daily for 56 days

Psoriasis Trial

- 10 subjects (for main part of study)
- Mild to moderate chronic plaque type psoriasis, for at least one year
- Target lesion must have
 - Severity Index score (LPSI) of 5-8
 - Area of 10 - 100cm²;
 - Stable in both extent and severity for two weeks prior to treatment

Definition LPSI: summed score for

- erythema, induration and desquamation of target lesion,
- scale of 0 – 12
- higher score = more severe disease
- decrease in LPSI score = improvement

Psoriasis Trial

Safety and Tolerability

- No Serious Adverse Effects
- 16 AE's reported
- Ranging mild to severe (one subject had severe cold and sore throat)
- All classified as not related or unlikely to be related
- Include back pain, headache, sinusitis, head cold, common cold, inflamed psoriasis (1 subject)

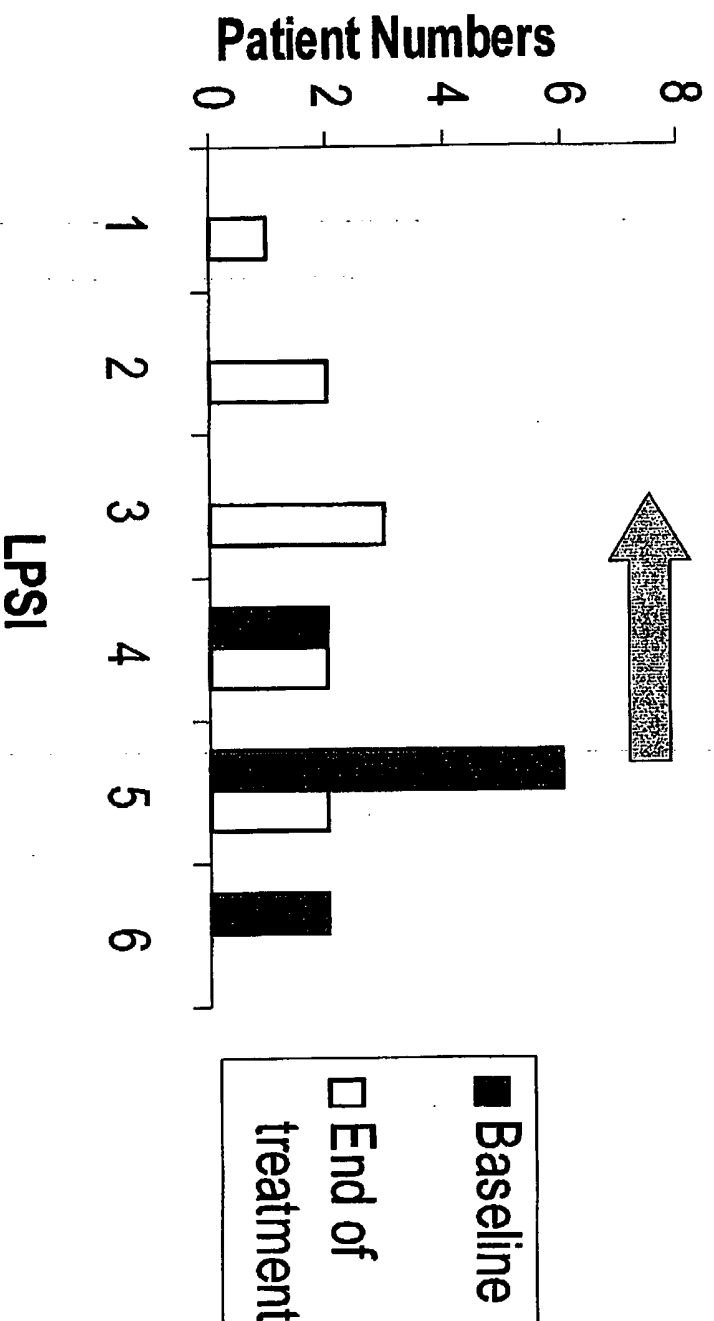
Psoriasis Trial

Disease Assessment

- 9/10 patients had improved LPSI score by the end of study
- 1 patient showed improvement of 4 points,
- 4 patients improved by 2 points, and
- 3 patients improved by 1 point
- 8 patients reported improvement in their subjective assessment of the psoriatic lesion

Psoriasis LPSI scores

Lower LPSI scores indicate improvement



Psoriasis Trial Summary

- PMX53 Gel (10mg/ml) is safe and tolerable over 56 days
- Data indicates a moderate clinical response

RA Trial Interim Analysis

**A double-blind study evaluating the
safety of PMX53 in comparison to
placebo in patients with active
rheumatoid arthritis**

RA Trial Objectives

Primary objective:

Evaluate the safety and tolerability over 28 days dosing (recall Phase Ia single dose safety study)

Secondary objective:

Assess pharmacokinetics of PMX53 in acute and chronic dose setting

Assess biological activity

- synovial biopsy tissue assessment (only at end of study)
- Biochemical markers - CRP, ESR,
- Standard disease measures
- Physician assessment of disease
- Patient self assessment of disease, health and pain

RA Trial Protocol

- Randomised, double blind and placebo controlled
- 10 patients with active rheumatoid arthritis on methotrexate for 3 months and a stable dose (5-30 mg/week) for at least one month

Active disease defined as

= 6 tender and = 6 swollen joints AND ESR = 28mm/hr
or CRP = 10mg/L
or morning stiffness = 45 minutes

- Daily oral dose of 8 mg/kg for 28 days (*recall Phase Ia max single dose 10 mg/kg*)
- Safety evaluation: continuous throughout study
- PK profile Day 1 & Day 27 – trough levels days 7, 14

PMX53 was Safe and Tolerable

- **PMX53 group (n = 7)**
 - Total No. AEs = 9 across all patients (3 patients no AE's)
 - 2 patients had “moderate” severity AEs - both “unlikely” relationship
 - 4 patients had 7 “mild” severity AEs, 1/7 classed as “possibly” related
- **PLACEBO group (n = 3)**
 - Total No. AEs = 13
 - All mild, 6/13 classed as “possibly” related to drug

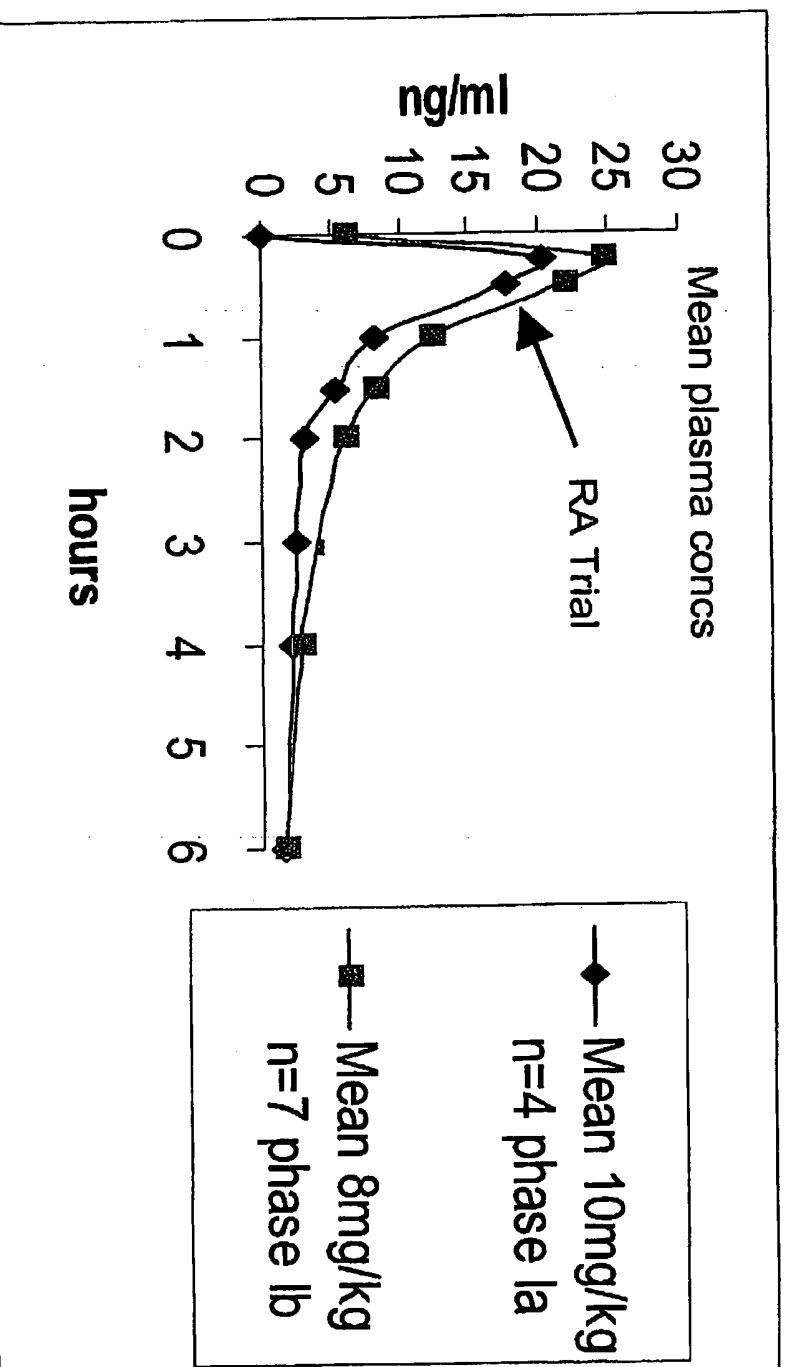
*** Primary Objective of Study likely to be achieved**

PMX 53 Pharmacokinetics

- PK profiles similar to that seen in healthy volunteers
- Blood levels typically higher
- Observe same wide variation between subjects with C_{max} ranging from 1 – 40 ng/ml
- No accumulation seen with chronic dosing

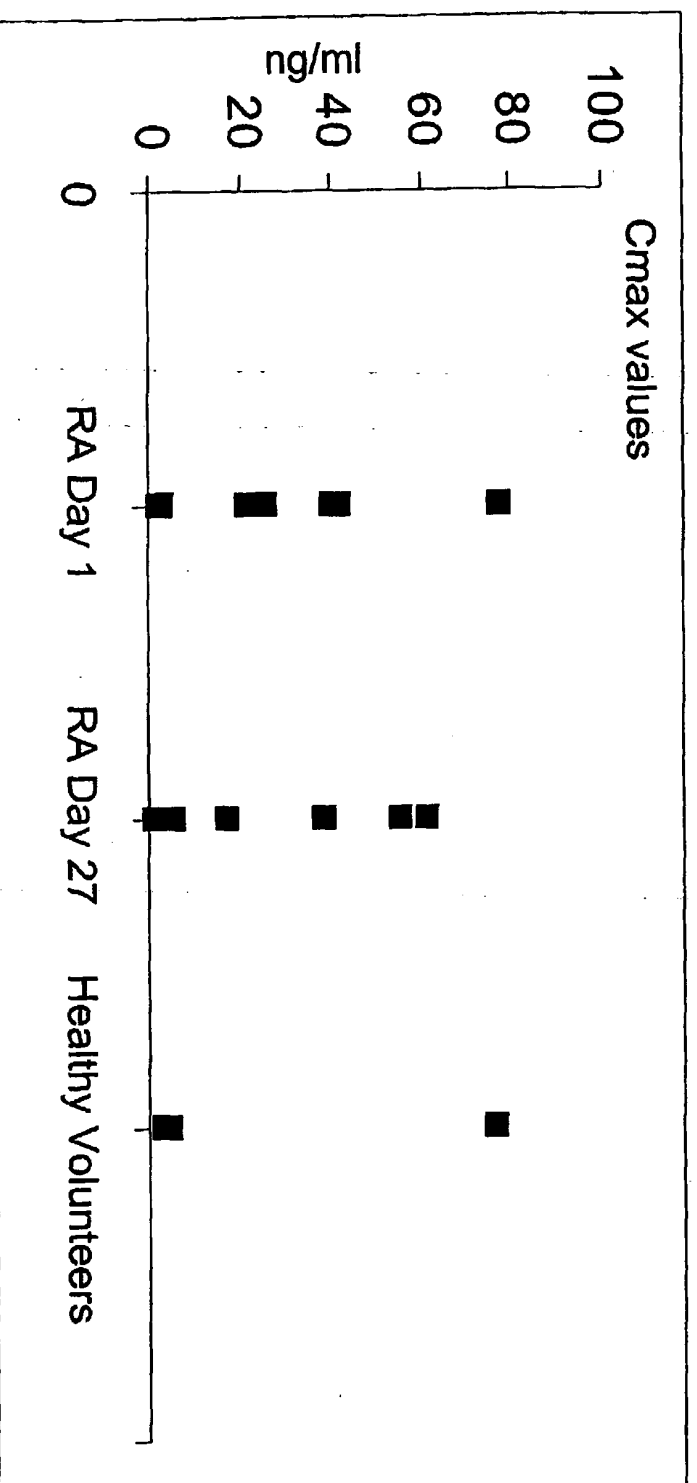
PMX 53 Pharmacokinetics

PK Profiles similar across studies



PMX 53 Pharmacokinetics

Range Cmax values



Wide interpatient variability / inpatient consistent

RA Trial Disease Measures

- Patients with elevated baseline CRP
 - 4/4 subjects on PMX53 showed decrease
 - 1/1 subjects on placebo showed increase
- ESR
 - No change observed
- Clinical
 - No trends observed in tender and swollen joints

RA Trial Disease Measures

- Patient Assessment
 - Patient Global Assessment of disease (VAS).
 - PMX 53 all patients showed an increase in assessment with 2 showing = 10 points improvement
 - All placebos showed worsening of at least 10 points
 - Patient Assessment of Health (VAS)
 - PMX53 recorded improvement in 3/7 patients
 - Placebo recorded worsening in 3/3 patients
 - VAS pain score
 - PMX53 3/7 (42%) less pain 4/7 unchanged
 - Placebo 1/3 (33%) less pain 2/3 worsened
- Physician Assessment (VAS)
 - PMX53 3/7 (42%) improved and 4/7 unchanged
 - Placebo 1/3 (33%) improved 2/3 worsened

RA Trial Sub-study

- Ex-vivo Blood Study (“Reedquist Study”)

Analysis of Leukocyte Function and Survival

- Blood samples taken from all patients at
 - Baseline, post 6hr, trough day 7, 14 and Day 27
- Large inter- and intra-patient variation in control data observed in placebo treated patients
- Against this background variability it is impossible to interpret data

RA Trial Interim Results Summary

- No safety issues to hinder continuation of study
- Highly likely to reach primary endpoint of safe and tolerable dosing over 28 days
- PK profile replicates phase I healthy volunteer study
 - Increased frequency of higher blood plasma levels
 - Large interpatient variation
 - Low inpatient variation
- Some disease assessments showing moderate positive trends
- Ex-vivo blood analysis disappointing due to technical issues
- Key biological markers from synovial tissue biopsy to be analyzed at end of study

RA Trial Progress

- A total of 14 subjects have completed treatment and 1 is currently on study
- A further 4 patients identified for study and awaiting prescreening
- Aiming to recruit a total of at least 20 subjects as fast as possible

ALTERNATE OPTION cont...

- Subcutaneous dosing with PMX53

If Phase I s.c study positive

- Provides licensee clear path for development
- Takes oral delivery form off critical path

Downside

limit potential clinical use to short term indications eg
IBD relapse, treatment of acute inflammatory
episodes

ALTERNATE OPTION...

- Subcutaneous dosing with PMX53
 - subcutaneous preclinical data shows sustained blood levels over many hours
 - Preclinical rats and dogs data demonstrate efficacy at dose levels of 0.3 mg/kg
 - Positive for COGS issue
- Work up to human phase I study to show:
 - Sustained blood levels
 - .. addresses "bioavailability/transient" PK issue
 - If available assess also using biomarker assessment

PLAN GOING FORWARD...

Continue to develop Biomarker for PMX53

- Option 1 Oxidative Burst Assay
 - Questions regarding sufficient sensitivity to detect activity?
 - Inter- and Intra-assay data adequate to show effect?
 - Assay work ongoing at Promics labs
- Option 2 LPS Model
 - Clinical trials using LPS challenge have been conducted
 - Requires validation in preclinical before assessing healthy volunteer study
 - Ongoing assessment at Promics labs

Two major challenges remain...

- Demonstration of adequate and sustained block of C5a receptors with PMX53 in face of transient PK profile
 - If +ve disease efficacy....resolved v
 - If disease efficacy equivocalneed biomarker data
- Estimation of Cost of Goods
 - Highly dependent on dose required
 - Use biomarker to estimate efficacious doses required

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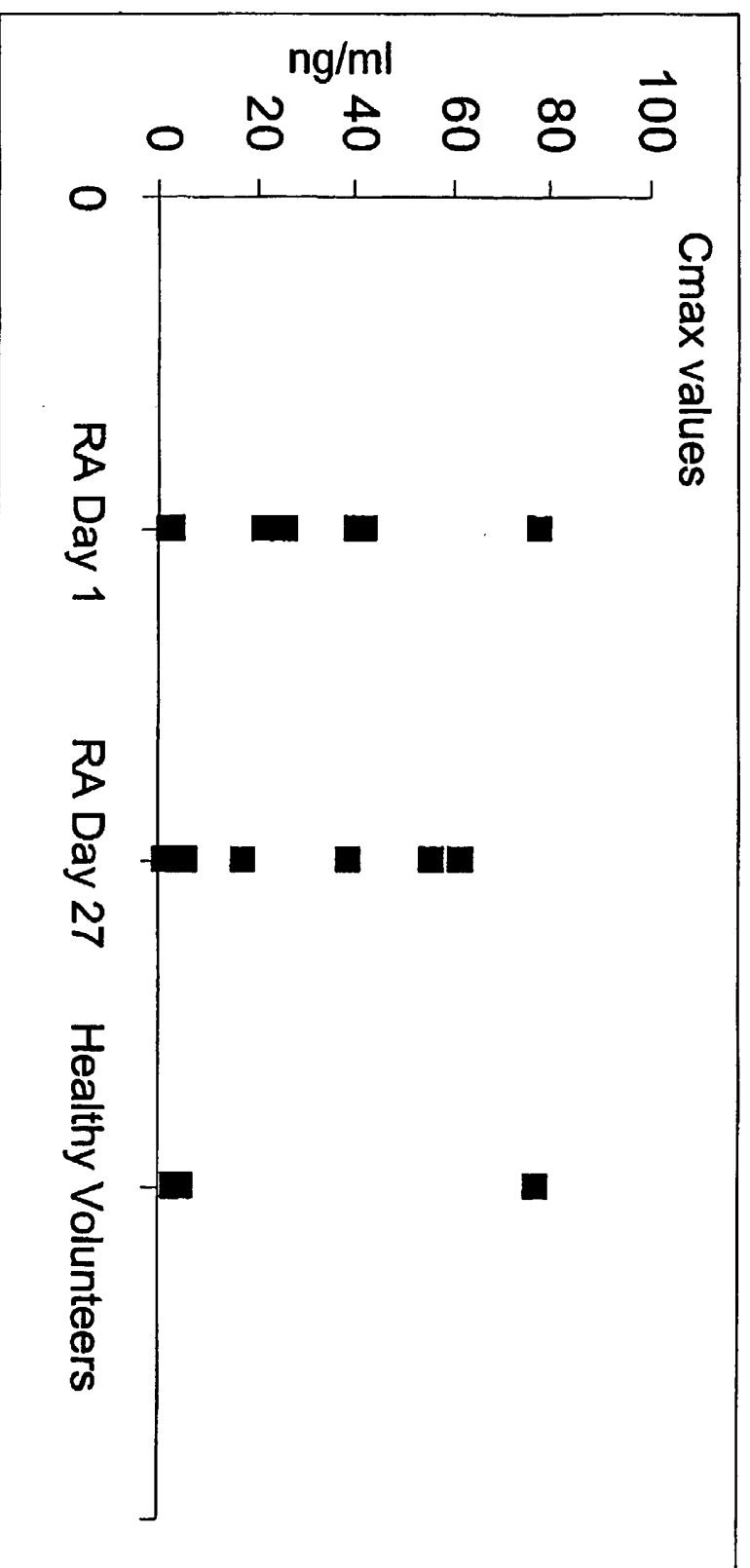
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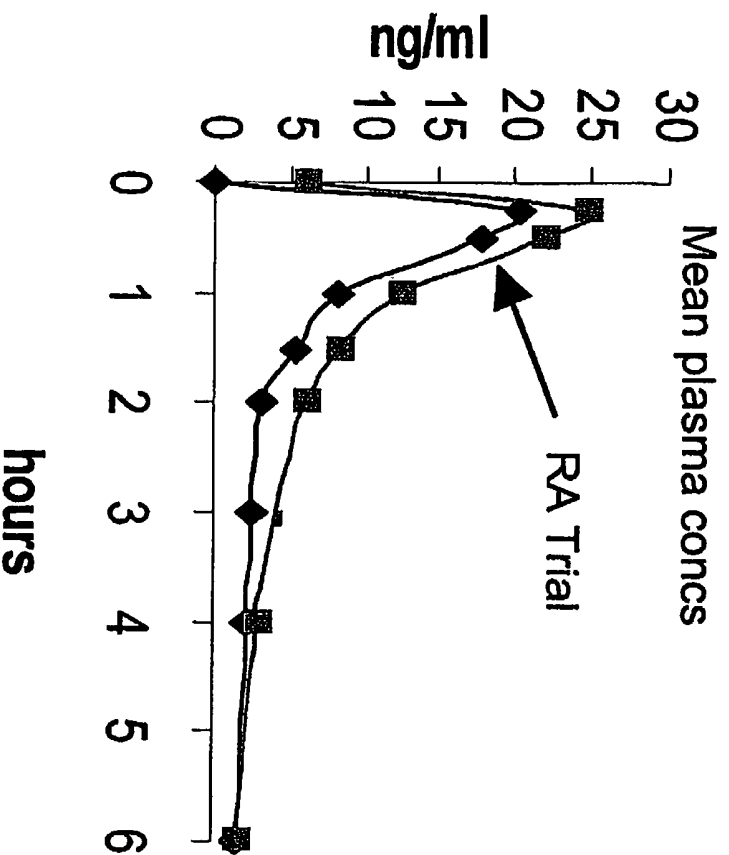
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—◆— Mean 10mg/kg
n=4 phase Ia

—■— Mean 8mg/kg
n=7 phase Ib

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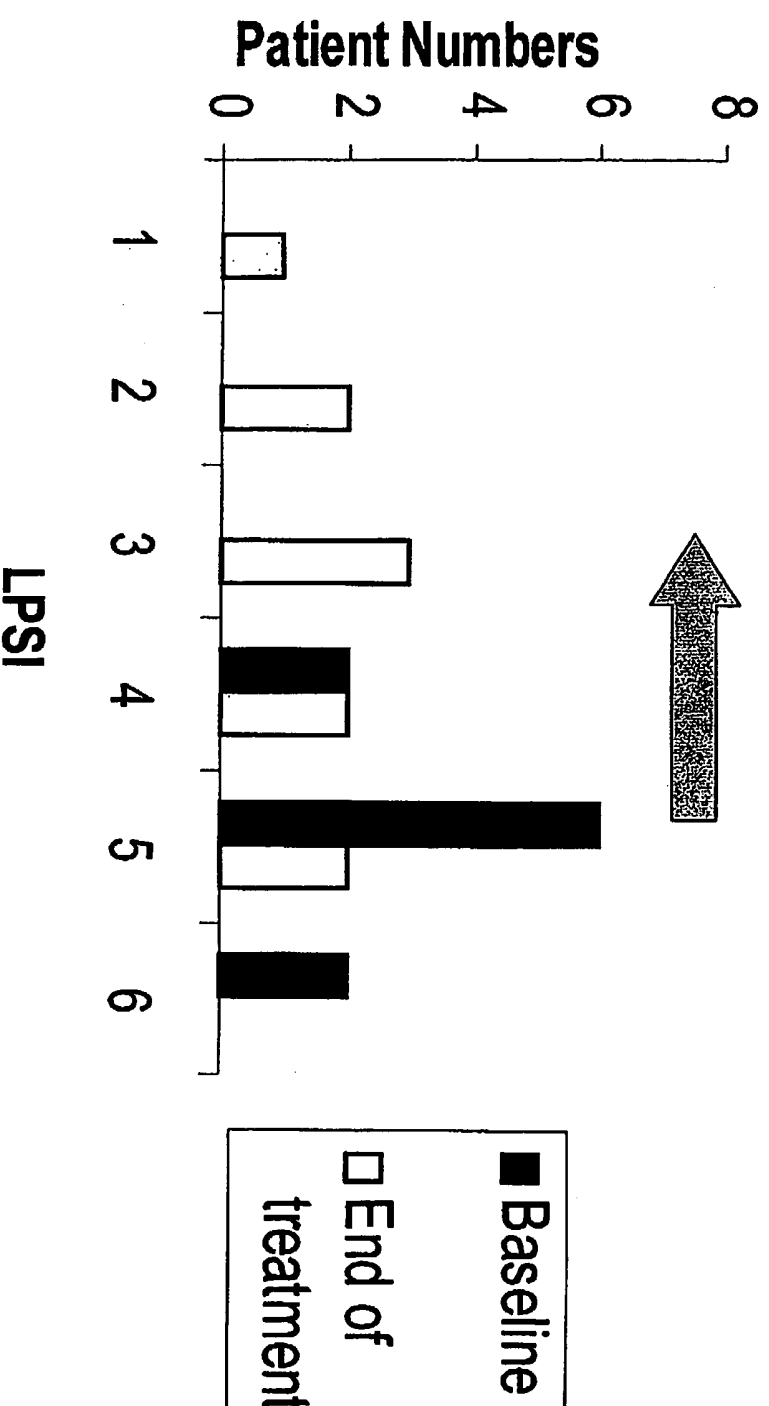
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PRM-01-03

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PROMICS DEVELOPMENT REPORT – February 2004

- PRM-01-03 Psoriasis Study Results
- PRM-01-02 RA Interim Data
- Update on Technology Development Plan

March 2004 Development Report

Arthritis Trial

- Recruitment
 - 16 are currently on study
 - 1 subject awaiting screening results
 - 2 further subjects identified as possibility for screening
- Timelines
 - Site committed to complete treatment of all subjects (approximately 20) by end May
 - Synovial tissue processing to be completed within subsequent two months
 - Plan to visit site in the first week of August to discuss interpretation of unblinded data with investigator
 - Full clinical data planned for August board meeting

Formulation of oral dose

- Four companies specialising in solid dose formulation have been approached regarding the development of a formulated oral dose for PMX53
- Proposals have been requested for formulation work that will attempt to:
 - Provide consistent blood levels and minimise subject to subject variation
 - Maximise stomach absorption and bioavailability
- Costing, timelines and recommendations for this contract development to be prepared over next month

Biomarker Development

- Oxidative Burst
 - Promics laboratory have conducted assay validation
 - Data indicates that the assay continues to have considerable assay to assay variation
 - Based on these results it is recommended that the use and investigation of this biomarker in a healthy volunteer study be postponed at least till an improved or alternative formulation of PMX53 is developed
- Alternative LPS model
 - There is precedent for use of this model in healthy volunteer studies to assess activity of new drugs, using clinical and/or cytokine measurements
 - Promics laboratory is investigating viability of this model with PMX53 over the next few months in rats and dogs

Additional development priorities

- Investigate the possibility of alternative manufacturers for PMX53 in China and India with the purpose of addressing Cost of Goods issues
- New formulations for subcutaneous delivery of PMX53 will be tested in Promics laboratories to address injection site toxicity observed in safety and toxicity studies
 - Subcutaneous delivery may present an alternative route of administration and development by a potential purchaser and be appropriate for treatment of some acute inflammatory disorders. This route of administration may also address bioavailability and COGs issues